

[0028] The present invention provides an improved endoluminal prosthesis comprising a polytetrafluoroethylene tubular member with a luminal surface, an exterior surface, and a longitudinal axis. A diametrically deformable stent is circumferentially disposed on the surface of the tubular member. The stent is formed from an elongate wire helically wound defining a plurality of spaced apart windings disposed at a first angle with respect to said longitudinal axis. An elongate securement member secures the stent to said tubular member, the securement member is helically arranged at a second angle with respect to said longitudinal axis so that said first angle is not congruent to said second angle.

[0029] The design allows securement of a stent to a graft in such a manner to ensure optimal properties of flexibility and reduced profile. Specifically, the helical angularly oriented direction of the securement member, which is wrapped circumferentially around the tubular member creates an angle with respect to the longitudinal axis of the tubular member which is incongruous to the angle at which the windings of the stent are disposed with respect to the longitudinal axis of the prosthesis. This allows for structural integrity of the prosthesis with a minimal amount of material comprising the securement member.

[0030] Various stent types and stent constructions may be employed in the present invention. Among the various stents useful include, without limitation, self-expanding stents and balloon expandable stents. The stents may be capable of radially contracting, as well, and in this sense can best be described as radially distensible or deformable. Self-expanding stents include those that have a spring-like action which causes the stent to radially expand, or stents which expand due to the memory properties of the stent material for a particular configuration at a certain temperature. Nitinol is one material which has the ability to perform well while both in spring-like mode, as well as in a memory mode based on temperature. Other materials are of course contemplated, such as stainless steel, platinum, gold, titanium, and other biocompatible metals, as well as polymeric stents.

[0031] Referring now to Figures 1 and 2 of the drawings, the composite prosthesis 5 of the present invention includes a stent 2 shown in Figure 1, as well as a similar stent 3 shown in Figure 2 of the drawings. Stent 2 is shown in a collapsed configuration in Figure 1. Stents 2 and 3 include a plurality of spaced apart windings 4 which include successive upper wave-like peaks 6 and lower wave-like peaks 8. The upper and lower wave-like peaks are connected via leg segments 10 of the stent. As seen in Figure 2, stent 3 shows parallel windings 4 arranged along the longitudinal axis of the prosthesis in such a manner that upper wave-like peaks 6 are nested within lower wave-like peaks 8 of adjacent windings along the stent. As used in this disclosure, the term nested refers to the stent configuration where successive upper wave-like peaks of the stent are linearly aligned to fit within the successive lower wave-like peaks of the stent so that each wave is stacked (or nested) within the next adjacent winding. The stent shown in Figure 1 is more fully described in commonly assigned U.S. Patent No. 5,906,639 to Rudnick, et al., herein incorporated by reference.

[0032] Referring to Figure 2 of the drawings, the tubular graft member 12 of the endoluminal prosthesis is preferably formed of polytetrafluoroethylene (PTFE). In vascular applications, prostheses are most often manufactured from expanded PTFE (ePTFE) tubes. As a result of the stretching and expansion of the PTFE material, these tubes have a microporous structure which allows natural tissue ingrowth and cell endothelialization once implanted in the vascular system. This contributes to long term healing and patency of the prosthesis. Tubular member 12 may be extruded as a tube or may be formed from an extruded sheet which is subsequently formed into a tubular structure. Textile or fabric constructions formed of PTFE or ePTFE yarns, filaments, or mesh may also be employed.

[0033] As shown in Figure 2, stent 3 is applied in a radially expanded condition about the exterior surface of tubular graft member 12 to form a stent/graft composite of the type well known in the art. While the preferred embodiments described herein show stent 2 supported about the exterior surface of tubular graft member 12, it is within the contemplation of the present invention to support the stent on the opposed luminal surface thereof.

[0034] Referring now to Figures 3 and 4, a composite stent/graft device 17 is shown. Device 17 includes a stent 14 positioned about an ePTFE tube 18. In the present example tube 18 is formed from a sheet of ePTFE. Stent 14 is similarly formed of spaced apart windings comprising successive upper wave-like peaks and lower wave-like peaks connected via leg segments of the stent. As can be seen in Figure 3, the upper wave-like peaks meet lower wave-like peaks of successive windings to form elbows of coincidence 16.

[0035] As mentioned above, diametrically deformable stent 14 is helically wound to define a plurality of spaced apart windings 15. Windings 15 are disposed at a first angle with respect to the longitudinal axis of the ePTFE tubular member. The longitudinal axis of tubular member 18 is shown with directional arrow 22. Successive windings 15 of stent 14 are positioned at a first angle (as shown with directional arrow 24) θ with respect to the longitudinal axis of tubular member 18.

[0036] The present invention provides a securement member 20 which is most preferably a flat, thin suture. Tape, thread, ribbon, or other elongate members may also be used. The securement member may be formed of a variety of materials. Securement member 20 is preferably less than 0.60 mm wide. The securement member is preferably made from a textile material. In using the term textile material in this disclosure, it is meant to indicate any material which may be used to combine with other pieces of the same material to become part of a larger piece of fabric. Some materials which may be used as the securement member include, but are not limited to PTFE, ePTFE, Polyethylene terephthalate (PET), Polyether ether ketone (PEEK), polypropylene, fluorinated ethylene propylene (FEP), nylon (polyamide), polyurethane (PU) and polyimide (PI), polybutylene terephthalate (PBT), polyurethane rubber (PUR), silicone and silicone rubber, and bio-absorbable materials, including poly(glycolic acid) (PGA), poly(lactic acid) (PLA).

[0037] As shown in Figure 4 of the drawings, securement member 20 is helically arranged